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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/557,823	04/25/2000	Richard J. Bucala	0203H	9900
24510	7590	08/12/2004	EXAMINER	
PIPER MARBURY RUDNICK & WOLFE LLP STEVEN B KELBER 1200 NINETEENTH STREET, NW WASHINGTON, DC 20036-2412			NOLAN, PATRICK J	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 08/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/557,823

### Applicant(s)

BUCALA ET AL.

### Examiner

Patrick J. Nolan

### Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 66-68, 73-75 and 81-89 is/are pending in the application.
- 4a) Of the above claim(s) 83, 84 and 86 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 66-68, 73-75, 81-82, 85, 87-89 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **Part III DETAILED ACTION**

1. Claims 66-68, 73-75 and newly added claims 81-89 are pending.
2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6-8-04 has been entered.
3. Newly submitted claims 83-84 and 86 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: assays drawn to indirect or direct detection techniques such as mass spectrometry or circular dichroism spectroscopy are patentably distinct from assays involving anti-MIF antibodies.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 83-84 and 86 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the

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international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 66-68, 73-75, 81-82, 85, 87-89 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,786,168. (AA on the IDS submitted 9-24-02), for reasons set forth in Paper No. 18.

Applicant's arguments filed 6-8-04 have been fully considered but are not found persuasive.

Applicant argues the prior art GIF and MIF are biologically distinct and so the prior art method of detecting GIF can not anticipate a claim drawn to detecting MIF.

However, the biological activities of the detected protein are not essential to perform the assay. All that is necessary is an antibody which specifically binds MIF, which the specification defines as SEQ ID NO. 5. Since the prior art teaches an antibody which specifically binds the claimed SEQ ID NO. 5, the claims are anticipated. Applicant has provided no evidence demonstrating the prior art antibody would not bind the currently claimed MIF protein. The prior art reference teaches making an antibody to a protein that has 100% amino acid sequence identity over the entire length to applicant's claimed MIF polypeptide. Absent direct evidence to the contrary, the prior art antibody would bind the claimed MIF polypeptide. There are no structural differences between the claimed MIF polypeptide and the prior art proteins, in other words the antigens used to raise antibodies in both the prior art and the instantly claimed invention are identical, so antibodies resulting from said immunization with said antigens would have the same antigenic specificity.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 66-68, 73-75, 81-82, 85, 87-89 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter

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which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

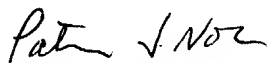
The '168 patent teaches a protein, GIF, which has 100% sequence identity to applicant's claimed MIF. Applicant clearly acknowledges that MIF and GIF are biologically distinct. However Applicant's specification does not demonstrate an antibody which can immunologically distinguish between GIF and MIF, and furthermore there are no teachings in the specification as to how one of skill in the art could raise such an antibody. When one of skill in the art practices Applicant's invention using the teachings of the specification, one would be simultaneously detecting GIF and MIF, since they are identical at the amino acid level. Since the simultaneous detection of MIF and GIF would not allow one of skill in the art to only detect MIF, and therefore practice the claimed invention, it would take an undue amount of experimentation to practice the invention as claimed.

6. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

7. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is 571-272-0847.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-272-0841.



Patrick J. Nolan, Ph.D.

Primary Examiner, Group 1640

August 10, 2004